



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Colman *et al.*

Appl. No. 10/080,713

Filed: February 25, 2002

For: **Method of Preparing a
Somatic Cell for Nuclear
Transfer**

Confirmation No. 9155

Art Unit: 1632

Examiner: *To Be Assigned*

Atty. Docket: 1966.0020003/EKS/BJD/FRC

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Information Disclosure Statement

Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language document AO1 cited on Form PTO 1449:

Document **AO1**, WO 98/06834, is in a foreign language. An English language abstract of document **AO1** is attached as document **AR40**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not

be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

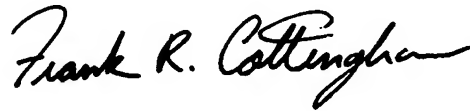
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

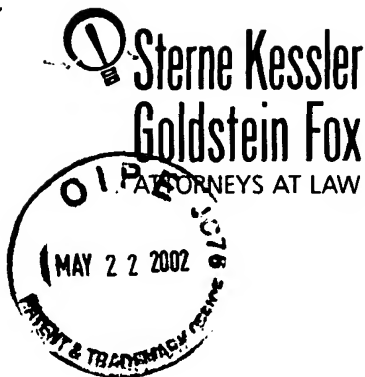
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Frank R. Cottingham
Attorney for Applicants
Registration No. 50,437

Date: 5/22/02

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600



Robert Greene Sterne
Edward J. Kessler
Jorge A. Goldstein
David K.S. Cornwell
Robert W. Esmond
Tracy-Gene G. Durkin
Michele A. Cimbalà
Michael B. Ray
Robert E. Sokohl
Eric K. Steffe
Michael Q. Lee
Steven R. Ludwig
John M. Covert
Linda E. Alcorn
Robert C. Millonig
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Patrick E. Garrett
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Kimberly N. Reddick
Theodore A. Wood
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Bruce E. Chalker
Joseph S. Ostroff
Frank R. Cottingham*
Christine M. Lhulier
Rae Lynn Pregelman*
Jane Shershenovich*
Lawrence J. Carroll*
George S. Bardmesser

Senior Counsel
Samuel L. Fox
Kenneth C. Bass III

Registered Patent Agents
Karen R. Markowicz
Andrea J. Kamage

Nancy J. Leith
Joseph M. Connolly
Ann E. Summerville
Helene C. Carlson
Gaby L. Longsway
Matthew J. Dove
Aaron L. Schwarz
Angelique G. Uy
Boris A. Matvenko
Mary B. Tung
Katrina Y. Pei
Bryan L. Skelton
Jason D. Eisenberg

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May 22, 2002

WRITER'S DIRECT NUMBER:
(202) 371-2615
INTERNET ADDRESS:
FRANKC@SKGF.COM

Commissioner for Patents
Washington, D.C. 20231

Art Unit 1632

Re: U.S. Utility Patent Application
Appl. No. 10/080,713; Filed: February 25, 2002
For: **Method of Preparing a Somatic Cell for Nuclear Transfer**
Inventors: Colman *et al.*
Our Ref: 1966.0020003/EKS/BJD/FRC

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Listing of the cited documents on Form PTO-1449 (41 sheets);
3. Copies of the one hundred thirty six (136) cited documents; and
4. Return postcard.

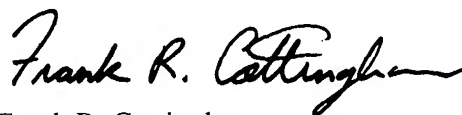
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
May 22, 2002
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Frank R. Cottingham
Attorney for Applicants
Registration No. 50,437

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Page 1 of 1

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1966.0020003/EKS/BJD/FRC

APPLICANT
Colman *et al.*

FILING DATE
February 25, 2002

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 97/07668	03/06/1997	WIPO			Yes No
	AM1	WO 97/07669	03/06/1997	WIPO			Yes No
	AN1	WO 97/37009	10/09/1997	WIPO			Yes No
	AO1	WO 98/06834	02/19/1998	WIPO			Yes No X
	AP1	WO 98/07841	02/26/1998	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	1	Alexander, L.J., <i>et al.</i> , "Complete sequence of the bovine β -lactoglobulin cDNA," <i>Nucl. Acids. Res.</i> 17:6739, IRL Press Ltd. (1989).
AS	1	Arbonés, M.L., <i>et al.</i> , "Gene targeting in normal somatic cells: inactivation of the interferon- γ receptor in myoblasts," <i>Nat. Genet.</i> 6:90-97, Macmillan Publishers Ltd (1994).
AT	1	Bertling, W.M., <i>et al.</i> , "Use of Liposomes, Viral Capsids, and Nanoparticles as DNA Carriers," <i>Biotech. Appl. Biochem.</i> 13:390-405, Academic Press Inc. (1991).

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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	98/27214	06/25/1998	WIPO			Yes No
	AM2	98/30683	07/16/1998	WIPO			Yes No
	AN2	98/37183	08/27/1998	WIPO			Yes No
	AO2	98/39416	09/11/1998	WIPO			Yes No
	AP2	99/01163	01/14/1999	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Brandon, E.P., <i>et al.</i> , "Targeting the mouse genome: a compendium of knockouts (part I)," <i>Curr. Biol.</i> 5:625-634, Current Biology Ltd. (1995).
	AS	2	Brandon, E.P., <i>et al.</i> , "Targeting the mouse genome: a compendium of knockouts (part II)," <i>Curr. Biol.</i> 5:758-765, Current Biology Ltd. (1995).
	AT	2	Brandon, E.P., <i>et al.</i> , "Targeting the mouse genome: a compendium of knockouts (part III)," <i>Curr. Biol.</i> 5:873-881, Current Biology Ltd. (1995).

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	AL3	WO 99/01164	01/14/1999	WIPO			Yes No
	AM3	WO 99/03981	01/28/1999	WIPO			Yes No
	AN3	WO 99/21415	05/06/1999	WIPO			Yes No
	AO3	WO 00/42174	07/20/2000	WIPO			Yes No
	AP3	WO 01/49106	07/12/2001	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>3</u>	Brehm, A., <i>et al.</i> , "Retinoblastoma protein recruits histone deacetylase to repress transcription," <i>Nature</i> 391:597-601, Macmillan Publishers Ltd. (February, 1998).
	AS	<u>3</u>	Brown, K.E., <i>et al.</i> , "Dynamic Repositioning of Genes in the Nucleus of Lymphocytes Preparing for Cell Division," <i>Mol. Cell</i> 3:207-217, Cell Press (February, 1999).
	AT	<u>3</u>	Buerstedde, J.M. and Takeda, S., "Increased Ratio of Targeted to Random Integration after Transfection of Chicken B Cell Lines," <i>Cell</i> 67:179-188, Cell Press (1991).

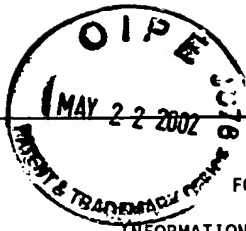
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	4	Campbell, K.H.S., <i>et al.</i> , "Nuclear-Cytoplasmic Interactions during the First Cell Cycle of Nuclear Transfer Reconstructed Bovine Embryos: Implications for Deoxyribonucleic Acid Replication and Development," <i>Biol. Reprod.</i> 49:933-942, Society for the Study of Reproduction (1993).
	AS	4	Campbell, K.H.S., <i>et al.</i> , "Cell cycle co-ordination in embryo cloning by nuclear transfer," <i>Rev. Reprod.</i> 1:40-46, Society for the Study of Fertility (1996).
	AT	4	Campbell, K.H.S., <i>et al.</i> , "Improved Development to Blastocyst of Ovine Nuclear Transfer Embryos Reconstructed during the Presumptive S-Phase of Enucleated Activated Oocytes," <i>Biol. Reprod.</i> 50:1385-1393, Society for the Study of Reproduction (1994).

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>5</u>	Campbell, K.H.S., <i>et al.</i> , "Sheep cloned by nuclear transfer from a cultured cell line," <i>Nature</i> 380:64-66, Macmillan Publishers Ltd. (1996).
	AS	<u>5</u>	Cao, X., <i>et al.</i> , "Effects of fibroblast-mediated interleukin 3 and interleukin 6 gene therapy on hematopoiesis in mice treated with 5-fluorouracil," <i>J. Mol. Med.</i> 76:782-789, Springer-Verlag (published online September, 1998).
	AT	<u>5</u>	Cherny, R.A. and Merei, J., "Evidence for Pluripotency of Bovine Primordial Germ Cell-Derived Cell Lines Maintained in Long-Term Culture," <i>Theriogenology</i> 41:175, Butterworth-Heinemann (1994).

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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 1966.0020003/EKS/BJD/FRC	APPLICATION NO. 10/080,713
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	<u>6</u>	Chen, W.Y., <i>et al.</i> , "Reactivation of silenced, virally transduced genes by inhibitors of histone deacetylase," <i>Proc. Natl. Acad. Sci. USA</i> 94:5798-5803, National Academy of Sciences (1997).	
AS	<u>6</u>	Christenson, R.K. and Day, B.N., "Maintenance of Unilateral Pregnancy in the Pig with Induced Corpora Lutea," <i>J. Anim. Sci.</i> 32:282-286, American Society of Animal Science (1971).	
AT	<u>6</u>	Cibelli, J.B., <i>et al.</i> , "Cloned Transgenic Calves Produced from Nonquiescent Fetal Fibroblasts," <i>Science</i> 280:1256-1258, American Association for the Advancement of Science (May, 1998).	

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>I</u>	Cibelli, J.B., <i>et al.</i> , "Transgenic bovine chimeric offspring produced from somatic cell-derived stem-like cells," <i>Nat. Biotechnol.</i> 16:642-646, Macmillan Publishers Ltd. (July, 1998).
	AS	<u>I</u>	Cole-Strauss, A., <i>et al.</i> , "Correction of the Mutation Responsible for Sickle Cell Anemia by an RNA-DNA Oligonucleotide," <i>Science</i> 273:1386-1389, American Association for the Advancement of Science (1996).
	AT	<u>I</u>	Colman, A. and Garner, I., "Transgenic Animals in Science and Industry," <i>Pharm. Forum</i> 5 (1996).

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AR	8	Deng, C. and Capecchi, M.R., "Reexamination of Gene Targeting Frequency as a Function of the Extent of Homology between the Targeting Vector and the Target Locus," <i>Mol. Cell. Biol.</i> 12:3365-3371, American Society for Microbiology (1992).
AS	8	Dominko, T., <i>et al.</i> , "Bovine Oocyte as a Universal Recipient Cytoplasm in Mammalian Nuclear Transfer," <i>Theriogenology</i> 49:385, Elsevier Science (January, 1998).
AT	8	Elsheikh, A.S., <i>et al.</i> , "Functional enucleation of mouse metaphase II oocytes with etoposide," <i>Jpn. J. Vet. Res.</i> 45:217-220, Hokkaido University (February, 1998).

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	AR	2	Evans, M.J. and Kaufman, M.H., "Establishment in culture of pluripotential cells from mouse embryos," <i>Nature</i> 292:154-156, Macmillan Publishers Ltd. (1981).
	AS	2	Finn, G.K., <i>et al.</i> , "Homologous Plasmid Recombination Is Elevated in Immortally Transformed Cells," <i>Mol. Cell. Biol.</i> 9:4009-4017, American Society for Microbiology (1989).
	AT	2	Fulka, J., <i>et al.</i> , "Cloning by somatic cell nuclear transfer," <i>BioEssays</i> 20:847-851, John Wilson & Sons, Inc. (October, 1998).

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	AR	<u>10</u>	Galili, U., <i>et al.</i> , "A Unique Natural Human IgG Antibody With Anti- α -Galactosyl Specificity," <i>J. Exp. Med.</i> 160:1519-1531, Rockefeller University Press (1984).
	AS	<u>10</u>	Gerfen, R.W. and Wheeler, M.B., "Isolation of Embryonic Cell-lines from Porcine Blastocysts," <i>Anim. Biotechnol.</i> 6:1-14, Marcel Dekker, Inc. (1995).
	AT	<u>10</u>	Griffiths, G.M., <i>et al.</i> , "Somatic mutation and the maturation of immune response to 2-phenyl oxazolone," <i>Nature</i> 312:271-275, Macmillan Publishers Ltd. (1984).

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	APPLICANT Colman <i>et al.</i>	
	FILING DATE February 25, 2002	GROUP 1632

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>11</u>	Hanson, K.D., <i>et al.</i> , "Analysis of Biological Selections for High-Efficiency Gene Targeting," <i>Molec. Cell. Biol.</i> 15:45-51, American Society for Microbiology (1995).
	AS	<u>11</u>	Hasty, P., <i>et al.</i> , "Gene targeting, principles, and practice in mammalian cells," in: <i>Gene Targeting: A Practical Approach</i> , Ed. Joyner, A.L., Oxford University Press, Oxford, England pp.1-36 (1992).
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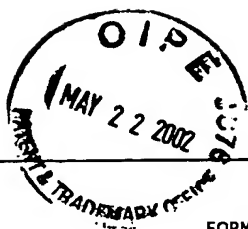
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	AR	<u>12</u>	Hyttinen, J.M., <i>et al.</i> , "High-level expression of bovine β -lactoglobulin gene in transgenic mice," <i>J. Biotechnol.</i> 61:191-198, Elsevier Science (May, 1998).
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	AT	<u>12</u>	Itzhaki, J.E., <i>et al.</i> , "Construction by gene targeting in human cells of a 'conditional' <i>CDC2</i> mutant that rereplicates its DNA," <i>Nat. Genet.</i> 15:258-265, Macmillan Publishers Ltd. (1997).

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AR	14	Kato, Y., <i>et al.</i> , "Eight Calves Cloned from Somatic Cells of a Single Adult," <i>Science</i> 282:2095-2098, American Association for the Advancement of Science (December, 1998).
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	AR	<u>15</u>	Kono, T., "Nuclear transfer and reprogramming," <i>Reviews Reprod.</i> 2:74-80, Journals of Reproduction and Fertility (1997).
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>16</u>	Kwon, O.Y. and Kono, T., "Production of identical sextuplet mice by transferring metaphase nuclei from four-cell embryos," <i>Proc. Natl. Acad. Sci. USA</i> 93:13010-13013, National Academy of Sciences (1996).
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>17</u>	Ma, T., <i>et al.</i> , "Generation and Phenotype of a Transgenic Knockout Mouse Lacking the Mercurial-insensitive Water Channel Aquaporin-4," <i>J. Clin. Invest.</i> 100:957-962, The American Society for Clinical Investigation Inc. (1997).
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	AT	<u>17</u>	Magnaghi-Jaulin, L., <i>et al.</i> , "Retinoblastoma protein represses transcription by recruiting a histone deacetylase," <i>Nature</i> 391:601-605, Macmillan Publishers Ltd. (February, 1998).

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	AP						Yes No

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	AR	<u>18</u>	Matsui, Y., <i>et al.</i> , "Derivation of Pluripotential Embryonic Stem Cells from Murine Primordial Germ Cells in Culture," <i>Cell</i> 70:841-847, Cell Press (1992).
	AS	<u>18</u>	McCreath, K.J., <i>et al.</i> , "Production of gene-targeted sheep by nuclear transfer from cultured somatic cells," <i>Nature</i> 405:1066-1069, Macmillan Publishers Ltd. (July, 2000).
	AT	<u>18</u>	McWhir, J., <i>et al.</i> , "Selective ablation of differentiated cells permits isolation of embryonic stem cell lines from murine embryos with a non-permissive genetic background," <i>Nat. Genet.</i> 14:223-226, Macmillan Publishers Ltd. (1996).

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	AR	<u>19</u>	Mitalipova, M., <i>et al.</i> , "Bovine Oocyte Cytoplasm Reprograms Somatic Cell Nuclei From Various Mammalian Species," <i>Theriogenology</i> 49:389, Elsevier Science (January, 1998).
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	AT	<u>19</u>	Müller-Ladner, U., <i>et al.</i> , "Gene Transfer Of Cytokine Inhibitors Into Human Synovial Fibroblasts In The SCID Mouse Model," <i>Arthritis Rheum.</i> 42:490-497, John Wiley and Sons, Inc. (March, 1999).

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	AR	<u>20</u>	Nickoloff, J.A. and Reynolds, R.J., "Transcription Stimulates Homologous Recombination in Mammalian Cells," <i>Mol. Cell. Biol.</i> 10:4837-4845, American Society for Microbiology (1990).
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	AT	<u>21</u>	Piedrahita, J.A., <i>et al.</i> , "Generation of Transgenic Porcine Chimeras Using Primordial Germ Cell-Derived Colonies," <i>Biol. Reprod.</i> 58:1321-1329, Society for the Study of Reproduction (May, 1998).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>38</u>	Yáñez, R.J. and Porter, A.C.G., "Therapeutic gene targeting," <i>Gene Ther.</i> 5:149-159, Stockton Press (February, 1998).
	AS	<u>38</u>	Zakhartchenko, V., <i>et al.</i> , "Nuclear Transfer in the Bovine Embryo: Developmental Potential of Cultured Adult Cells," <i>Theriogenology</i> 51:218, Elsevier Science (January, 1999).
	AT	<u>38</u>	Zhen, L., <i>et al.</i> , "Gene targeting of X chromosome-linked chronic granulomatous disease locus in a human myeloid leukemia cell line and rescue by expression of recombinant gp91 ^{phox} ," <i>Proc. Natl. Acad. Sci. USA</i> 90:9832-9836, National Academy of Sciences (1993).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1966.0020003/EKS/BJD/FRCAPPLICATION NO.
10/080,713APPLICANT
Colman *et al.*FILING DATE
February 25, 2002GROUP
1632

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>39</u>	Copy of U.S. Application No. 09/377,595, filed August 19, 1999, Kind, <i>et al.</i>
AS	<u>39</u>	Copy of U.S. Application No. 09/600,130, filed July 12, 2000, Campbell, K.H.S.
AT	<u>39</u>	Copy of U.S. Application No. 09/614,864, filed July 12, 2000, Colman, <i>et al.</i>

EXAMINER

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
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APPLICATION NO.
10/080,713

APPLICANT
Colman *et al.*

FILING DATE
February 25, 2002

GROUP
1632

U.S. PATENT DOCUMENTS

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>40</u>	Dialog File 351, Accession No. 11714391, Derwent WPI English language abstract for WO 98/06834.
	AS	<u>40</u>	Entrez NCBI, Genbank Report, Accession No. Z48305, Hyttinen, J.M., (1995).
	AT	<u>40</u>	Entrez NCBI, Genbank Report, Accession No. U89672, Lou, Y. and Holtz, A., (1997).

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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 1966.0020003/EKS/BJD/FRC	APPLICATION NO. 10/080,713
	APPLICANT Colman <i>et al.</i>	
	FILING DATE February 25, 2002	GROUP 1632

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	AR	41	Entrez NCBI, Genbank Report, Accession No. U89673, Lou, Y. and Holtz, A., (1997).
	AS		
	AT		

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